

S/N 10/532.975

Reply to Office Action of August 15, 2007

REMARKS

Favorable reconsideration of this application is requested. Claims 1, 7, 9 and 16 have been amended. The limitation in claims 1 and 9 concerning $(X-Y)/X$ and $\{X-(Y-Y')\}/X$ being in a range of -1.00 to 0.5 is supported by for example page 14, line 16 to page 15, line 1 and page 21, lines 1-4 of the specification. Claims 7 and 16 have been amended editorially. No new matter has been added. Claims 1-17 are pending.

Specification

The abstract has been amended editorially, taking the issues in the objection into account. Withdrawal of the objection is respectfully requested.

Claim Objections

Claim 7 has been amended editorially, taking the issues in the objection into account. Withdrawal of the objection is respectfully requested.

Claim rejections - 35 U.S.C. § 102

Claims 1-7 and 9-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Rabbani et al. (EP 0971039). Applicants respectfully traverse the rejection.

Claim 1 requires, in the absence of an intervening sequence between the sequence (Ac') on the 3'-end portion of the primer and the sequence (B') on the 5'-side of the sequence (Ac') of the primer, $(X-Y)/X$ to be in the range of -1.00 to 0.50, in which X denote the number of bases in the sequence (Ac') and Y denotes the number of bases in the region flanked by the sequences (A) and (B) on the target nucleic acid sequence. Claim 1 further requires, in the presence of an intervening sequence between the sequence (Ac') and (B'), $\{X-(Y-Y')\}/X$ to be in the range of -1.00 to 0.50, in which X and Y have the same meaning as above, and Y' denotes the number of bases in the intervening sequence. Claim 9 similarly requires, in the absence of an intervening sequence between the sequence (Ac') on the 3'-end portion of the first primer and the sequence (B') on the 5'-side of the sequence (Ac') of the first primer, $(X-Y)/X$ to be in the range of -1.00 to 0.50, and in the presence of an intervening sequence between the sequences (Ac') and (B'), $\{X-(Y-Y')\}/X$ to be in the range of -1.00 to 0.50. Claim 9 further requires, in the absence of an intervening sequence between the sequence (Cc') on the 3'-end portion of the second primer and the sequence (D') on the 5'-side of the sequence (Cc') of the second primer, $(X-Y)/X$ to be in the range of -1.00 to 0.50, and in the presence of an intervening sequence between the sequences (Cc') and (D'), $\{X-(Y-Y')\}/X$ to be in the range of -1.00 to 0.50, in which X denotes the number

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of bases in the sequence (Cc'), Y denotes the number of bases in the region flanked by the sequence (C) and (D) on the target nucleic acid sequence, and Y' denotes the number of bases in the intervening sequence. The advantageous effects of limiting X, Y and Y' as required by claims 1 and 9 are described as follows. In order to conduct efficient annealing of a new primer, it is necessary to allow the portion of the sequence (A) or (C) on the template nucleic acid to be single-stranded. Such a state requires the efficient formation of the stem-loop structure on the synthesized complementary nucleic acid. By limiting the values of X, Y and Y' as required by claims 1 and 9, efficient hybridization of the primer sequence on the 5'-side of (A) or (C) and the synthesized complementary sequence can be achieved (paragraph 73). As a result, amplification can be performed more efficiently (see page 13 line 23 to page 14, line 15).

The Examples provided in the specification illustrate the above described effects. Briefly, primers were prepared in accordance with claims 1 and 9. Amplification under isothermal conditions was conducted with different reaction times. The amplified products were then run on a gel and analyzed (see page 27, line 31 to page 44, line 35). As shown in Figures 5 to 10, primer sets with $\{X-(Y-Y')\}/X$ and $(X-Y)/X$ values in a range in accordance with claims 1 and 9 amplified more efficiently than those primer sets having $\{X-(Y-Y')\}/X$ and $(X-Y)/X$ values outside the range as required by claims 1 and 9 (compare primer sets 4 to 13 and 15 to 20, whose X, Y and Y' values are in accordance with claims 1 and 9, with primer sets 2 ($(X-Y)/X=1.00$) and 3 ($(X-Y)/X=0.7$).

Rabbani teaches FC and RC primers having first segments that are 29 and 30 bases respectively at the 3' end, and are capable of extensions using HBV target DNA as a template. The 30 bases at the 5' end of the FC and RC primers are second segments that are complementary to the first 30 bases synthesized by extension of the primers using HBV DNA as a template. Thus, the number of bases in the region flanked by the FC and RC primer annealing sequence and the hybridization sequence on the HBV DNA (corresponding to sequences A and B in claims 1 and 9) is 0. Accordingly, the FC and RC primers have $(X-Y)/X$ value of 1 ($(29-0)/29=1$; $(30-0)/30=1$). On the other hand, claims 1 and 9 require, in the absence of intervening sequence between the sequences (Ac') and (B'), $(X-Y)/X$ to be in the range of -1.00 to 0.50. Therefore, Rabbani does not anticipate claims 1 and 9. Moreover, the reference fails to teach or suggest limiting the range of $(X-Y)/X$ and $\{X-(Y-Y')\}/X$ as required by claims 1 and 9. In fact, the FC and RC primers correspond to the primer sets 2 and 3 in the Examples of the present

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specification. As shown in Figures 5 to 10, primer sets 2 and 3 do not amplify as efficiently as the primer sets in accordance with claims 1 and 9. Therefore, claims 1 and 9 and the dependent claims are patentable over Rabbani.

Claim rejections - 35 U.S.C. § 103

Claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbani in view of Kool, E.T. (Current Opinion in Chemical Biology (2000) 4: 602-608). Applicants respectfully traverse the rejection.

Rabbani has been distinguished above. Kool does not remedy the deficiencies of Rabbani. Therefore, claims 8 and 17 are patentable over the references taken alone or together. Applicants do not concede the correctness of the rejection.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

Double Patenting

Claims 1-4, 6, 7, 9-13, 15 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-12, 15 and 20-23 of copending Application No. 10/583,706. The rejection is rendered moot, as Applicants submit herewith a Terminal Disclaimer to overcome the rejection. Applicants, however, do not concede the correctness of the rejection, and reserve the right to submit arguments with respect to any of the rejected claims at a later time.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above, Applicant respectfully requests that a timely Notice of Allowance be issued on this case. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,



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